PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61F 7/00 | A1

(11) International Publication Number: WO 98/23236

(43) International Publication Date: 4 June 1998 (04.06.98)

(21) International Application Number: PCT/US97/21760

(22) International Filing Date: 24 November 1997 (24.11.97)

(30) Priority Data:
60/031,473 25 November 1996 (25.11.96) US

(71) Applicant: KINETIC CONCEPTS, INC. [US/US]; P.O. Box 659508, San Antonio, TX 78265-9508 (US).

(72) Inventor: VRZALIK, John, H.; 4444 Lane Street, San Antonio, TX 78263 (US).

(74) Agent: QUIRK, William, H.; Kinetic Concepts, Inc., P.O. Box 659508, San Antonio, TX 78265-9508 (US).

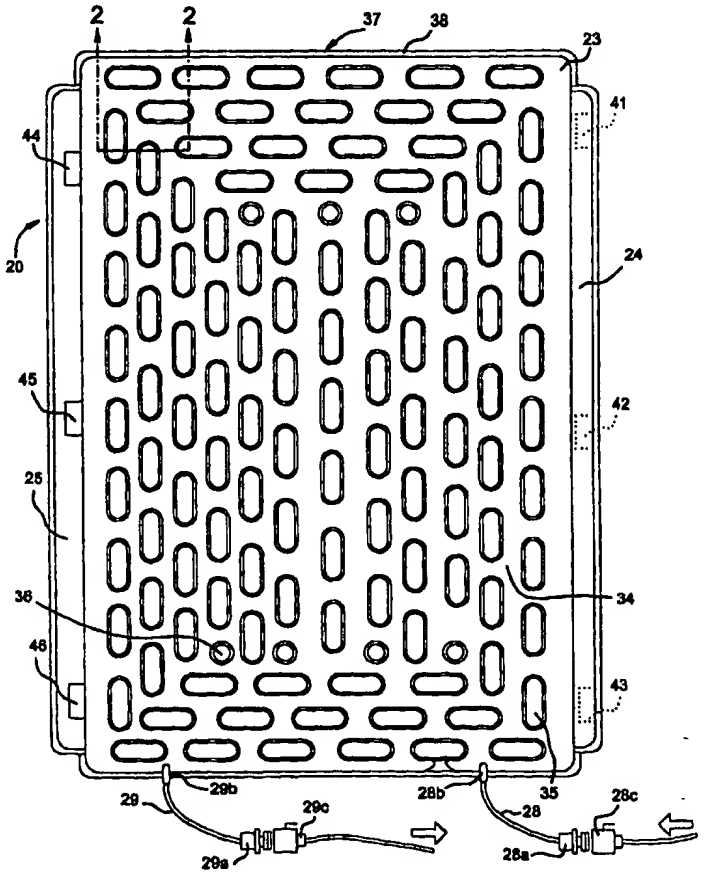
(81) Designated States: AU, CA, JP, MX, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.

(54) Title: TEMPERATURE CONTROL FOR USE WITH PATIENT SUPPORTS

(57) Abstract

This invention is a thermally controllable apparatus for use with a predetermined therapeutic support platform apparatus, and a thermic fluid producing device. Said apparatus includes a first side (30) configurative disposed adjacent the patient surface of the support platform, a second side (31) disposed adjacent a patient, and having a first portion (33a) thereof sealably connected to a first portion (33b), the first side (30), and a second portion (33d) thereof spaced from a second portion (33c) of the first side (30) such that there is formed a pocket (34) therebetween, valve means (28, 29) operably connected to the pocket and to the thermal fluid producing device to permit fluid flow therebetween, and a method of using the same.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	**ES**	Spain	**LS**	Lesotho	**SI**	Slovenia
AM	Armenia	**FI**	Finland	**LT**	Lithuania	**SK**	Slovakia
AT	Austria	**FR**	France	**LU**	Luxembourg	**SN**	Senegal
AU	Australia	**GA**	Gabon	**LV**	Latvia	**SZ**	Swaziland
AZ	Azerbaijan	**GB**	United Kingdom	**MC**	Monaco	**TD**	Chad
BA	Bosnia and Herzegovina	**GE**	Georgia	**MD**	Republic of Moldova	**TG**	Togo
BB	Barbados	**GH**	Ghana	**MG**	Madagascar	**TJ**	Tajikistan
BE	Belgium	**GN**	Guinea	**MK**	The former Yugoslav Republic of Macedonia	**TM**	Turkmenistan
BF	Burkina Faso	**GR**	Greece			**TR**	Turkey
BG	Bulgaria	**HU**	Hungary	**ML**	Mali	**TT**	Trinidad and Tobago
BJ	Benin	**IE**	Ireland	**MN**	Mongolia	**UA**	Ukraine
BR	Brazil	**IL**	Israel	**MR**	Mauritania	**UG**	Uganda
BY	Belarus	**IS**	Iceland	**MW**	Malawi	**US**	United States of America
CA	Canada	**IT**	Italy	**MX**	Mexico	**UZ**	Uzbekistan
CF	Central African Republic	**JP**	Japan	**NE**	Niger	**VN**	Viet Nam
CG	Congo	**KE**	Kenya	**NL**	Netherlands	**YU**	Yugoslavia
CH	Switzerland	**KG**	Kyrgyzstan	**NO**	Norway	**ZW**	Zimbabwe
CI	Côte d'Ivoire	**KP**	Democratic People's Republic of Korea	**NZ**	New Zealand		
CM	Cameroon			**PL**	Poland		
CN	China	**KR**	Republic of Korea	**PT**	Portugal		
CU	Cuba	**KZ**	Kazakstan	**RO**	Romania		
CZ	Czech Republic	**LC**	Saint Lucia	**RU**	Russian Federation		
DE	Germany	**LI**	Liechtenstein	**SD**	Sudan		
DK	Denmark	**LK**	Sri Lanka	**SE**	Sweden		
EE	Estonia	**LR**	Liberia	**SG**	Singapore		

TEMPERATURE CONTROL FOR USE WITH PATIENT SUPPORTS

BACKGROUND OF THE INVENTION

Related Applications:

This Application is a continuation of Applicant's copending U.S. Provisional Patent Application Serial No. 60/031,473 filed November 25, 1996. This Application claims domestic priority under 35 U.S.C. § 119 (e)(1).

Field of the Invention

The present inventions relate to apparatus and methods for affecting a patient's body temperature, particularly for therapeutic applications. Although there may be broader applications such as with heating pads and the like, the present inventions relate primarily to cooling pads and systems for lowering a patient's body temperature. Intended fields include applications for patients with diminished health and for patients using therapeutic supports such as oscillating treatment platforms, pressure reducing mattresses, and low air loss beds, to name a few.

Background Art

Various types of devices have long existed for cooling and heating patients without much regard for accommodating other health care needs. Such devices typically use a heat exchanger in a form of a flexible pad that can be positioned close to the patient's skin. Because of the way the pads work, they have traditionally been fluid impervious, which can trap moisture (i.e., condensation, sweat, incontinence, etc.) in close proximity to a patient's skin.

High moisture levels, however, tend to promote maceration and skin-breakdown. To make matters worse, the lower temperatures induced by cooling pads might naturally constrict a patient's capillaries, which may reduce the flow of oxygen and nutrients to the skin. Such effects would be of particular concern in patients who have poor skin condition or compromised circulation from the start. Hence,

conventional cooling pads may create an environment that is less than ideal for skin care.

For many of the same patient populations, there have also long been many types of specialized patient supports adapted to facilitate skin care. Two notable types of specialized therapeutic supports are (i) pressure reducing mattresses for reducing the pressures exerted by a mattress against a patient's skin (referred to as "interface pressures"), and (ii) oscillating treatment platforms for rotating patients from side-to-side. (For present purposes, low air loss mattresses and other pressure *relieving* mattresses are grouped together with pressure reducing mattresses.) Commercial examples of pressure reducing mattresses are available through KCI Therapeutic Services, Inc. of San Antonio, Texas, under the "THERAREST" (for composite foam mattresses) and "FIRST STEP" (for low air loss mattresses) trademarks. Detailed descriptions of particular pressure reducing mattresses may be found in U.S. Patent No. 5,022,110 issued June 11, 1991 (Stroh), and U.S. Patent No. 3,644,950 issued February 29, 1972 (Lindsay).

Oscillating treatment platforms are useful in treating and/or preventing a wide range of illnesses and conditions. Such a platform is particularly useful in addressing complications that may be encountered with immobile patients, including bed sores and other skin problems. By automatically rotating the patient from one lateral side to the other on a periodic basis, interface pressures at any particular location are likewise varied. As always, though, excess moisture near the patient's skin site tends to increase the likelihood of further skin problems. Commercial examples of oscillating treatment platforms are available through KCI Therapeutic Services, Inc. of San Antonio, Texas, under the "ROTO REST" trademark. Particular examples are also described in U.S. Patent No. 3,343,165 issued on March 25, 1969 (Keane) and U.S. Patent No. 4,175,550 issued on November 27, 1979 (Leininger et al.).

The descriptions (including drawings) of each of the above patents and all other patents referenced elsewhere in this application are incorporated herein by this reference, as though set forth in their entirety.

Despite the importance and high costs of skin care, the need to use hyper-hypothermia pads often overrides any concerns about the moist skin climate often associated with use of such pads. As a consequence, the therapeutic benefits of a patient's specialized support may be diminished. Consider low air loss ("LAL") mattresses, for instance. Perhaps the most important benefit of a LAL mattress is the slow but continuous evacuation of moisture vapor from adjacent the skin. Typical LAL mattresses support the patient with air cushions made from vapor-permeable fabrics. The vapor permeable material allows moisture vapor near the skin to pass away from the skin, and a continuous flow of air keeps the cushions inflated while also evacuating the moisture vapor that has passed through the fabric. Such benefits are significantly impeded by introducing a fluid impervious cooling pad between the patient and the LAL cushions.

As can be seen, although numerous specialized patient supports are generally useful in minimizing skin breakdown and in otherwise treating or preventing various ailments, there remains a need to improve such products and the conditions under which they may be used. There is also a therapeutic as well as a comfort need to improve thermal pads and the environments in which they are used.

SUMMARY OF THE INVENTIONS

It is a basic object of the present inventions to promote patient health by improving available therapies. This object may be addressed in part by improving devices for patient temperature control, such as by improving the functionality, efficiency, ease-of-use, comfort, safety and effectiveness of such devices.

It is another basic object to improve patient supports, particularly by enabling patient temperature control as an adjunct to other benefits of patient supports. It is a related object to enable patient temperature control using cooling pads and the like without compromising patient skin condition or impeding other therapies, including low air loss therapy and continuous lateral rotation therapy.

Accordingly, the present invention is directed in part to patient temperature control on a patient support. Such control may include use of a thermal sheet (such as

a pad or blanket) through which a liquid heat transfer medium is circulated. The sheet will typically define two types of passages -- an enclosed array of liquid passages for directing the heat transfer medium, and cross passages or the equivalent for passage of other fluids from one face of the sheet to the other. As gas passages, the cross passages permit air and/or moisture vapor to pass from one side of the sheet to the other, thereby addressing many objects including the object of enabling the provision of thermal control as an adjunct to low air loss therapy. As an open hole or the like, the cross passages may also permit liquids such as condensation, sweat, body fluids, etc. to pass away from a patient's skin, thereby minimizing maceration and skin breakdown.

Embodied as an under-patient pad, one face of the sheet may face the patient while the opposite sheet faces the patient support. The sheet will typically be formed by welding the two faces together in a way that forms a plurality of pocket passages therebetween. Liquid and/or vapor cross-passages or other types of openings are formed between the pocket passages. Lines are provided to operably connect the pocket passages with a conventional hyper-hypothermia unit to permit fluid flow therethrough. Hook and Loop tabs are provided at opposite ends of the pad for anchoring or so that the pad may be combined with other similar pads to affect a larger surface area.

The thermal control sheet may be configured to wrap around at least a part of the patient in certain applications. Alternating flows may also be used. The invention also includes various therapeutic methods for facilitating patient care.

Many objects and advantages will be readily apparent to those skilled in the art upon viewing the drawings and reading the detailed description hereafter, particularly when considered in light of the appended claims and the related art.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a plan view of the cooling pad which represents one preferred embodiment of various aspects of the present invention.

FIG. 1A is a plan view of the cooling pad which is distinguished from the cooling pad of FIG. 1 principally by the inclusion of flow-directing welds.

FIG. 2 is a partial cross-sectional view of the cooling pad shown in the plan view in FIG 1.

FIG. 3 is a plan view of the cooling pad as operatively implemented together with two other identical pads for cooling a patient (shown in phantom line) supported on a mattress (shown in dashed line).

FIG. 4 is a partial, headward perspective view of an oscillatory patient support platform having four cooling pads operatively positioned thereon, representing alternate embodiments of various aspects of the present invention.

FIG. 5 is a plan view of a cooling pad which is a thermally controlled leg wrap, which is another embodiment of this invention.

FIG. 5A is a cross-sectional view of the cooling pad as viewed in the plan view of FIG. 5.

FIG. 6 illustrate a typical application of a thermally controlled leg wrap utilizing a pressure reduction insert.

FIG. 7 illustrates a typical thermally controlled mid-section wrap.

FIG. 8 illustrates a typical thermally controlled mid section wrap with a rectal pressure reduction insert.

FIG. 9 illustrates a typical thermally controlled upper body wrap with a thoracic cushion insert.

FIG. 10 illustrates a typical thermally controlled head wrap with a cranial pressure reduction cushion.

FIG. 11 illustrates another embodiment of the cooling pad which employs multiple layers of liquid passages and provides for air exchange through the wrap.

FIG. 11A is a cross-sectional view of the cooling pad which is illustrated as FIG. 11.

FIG. 12 is a headward perspective of an oscillatory therapeutic support platform.

FIG. 13 illustrates a schematic of typical thermally controlled body wraps utilizing a hyper-hypothermia fluid producing and distribution device.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Various preferred embodiments are described below. These embodiments collectively represent notable innovations for cooling patients in conjunction with various patient supports such as mattresses, beds, seat cushions and the like. For the most part, these descriptions first describe structure and manufacture of the embodiments and then describe their typical use and some of the benefits of their structure in connection with such use. Referring to the drawings, FIGS. 1 and 2 show detailed aspects of a cooling pad 20 that represents one preferred embodiment of various aspects of the present invention. Pad 20 generally comprises heat exchanger 23, integral tabs 24 and 25, and liquid lines 28 and 29.

As viewed in Fig. 1, heat exchanger 23 is generally rectangular in shape. The longer dimension of heat exchanger 23 is approximately thirty inches, which is slightly less than the width immersion of most standard hospital bed mattresses. The shorter dimension of heat exchanger 23 is approximately 20 inches.

Heat exchanger 23 and its integral tabs 24 and 25 are composed primarily of a flexible, RF-weldable material suitable for containing and directing the flow of liquids such as may be used for cooling patients. Water, at temperatures and pressures such as are generated by conventional hyper-hypothermia units, is a preferred cooling liquid to be circulated through heat exchanger 23. The embodiment of FIG. 1 is formed primarily from ten-mil PVC sheets 30 and 31, (FIG. 2). Absent modifications described further herein, the two sheets 30, 31 are substantially identical to each other and are RF-welded together and cut in a manner that provides a relatively flat array 37 of passages 34 bound by welds 33.

The array 37 preferably has a shape and configuration substantially as shown in FIG. 1, which is adapted to promote circulation of cooling liquid throughout each of the liquid passages 34. The array 37 of liquid passages 34 defines a corresponding

array of oblong holes 35 and circular holes 36 between the liquid passages 34. When passages 34 are filled with cooling liquid, welds 33 and holes 35, 36 give the effect of an array of dimples arranged between the passages 34 that ensure substantially uniform thickness of the pad 20. As can be seen in FIG. 1, pad 20 is provided with 123 oblong dimples 35 and seven circular dimples 36, although various configurations and assortment of dimples (or holes) 35, 36 can be utilized. The particular pattern of dimples shown tends to orient the longitudinal dimension of oblong dimples 35 parallel with the closest outer edge of array 37. Such orientation is thought to promote better circulation of heat transfer liquid from inlet port 28b throughout the entirety of array 37 before exiting the array outlet port 29b. Various additional welds 54, 55 such as shown in FIG 1A may be utilized to help promote the circulation throughout the entire array 37. FIG. 1A is a plan view of cooling pad 20, which is distinguished from cooling pad 20 of FIG. 1 principally by the inclusion of flow-directing welds. Formation of such flow-directing welds, including auxiliary division welds, may require some experimentation to obtain proper radiuses and locations through optimized strength and durability of the pad as a whole, as will be known to those of skill in the art. FIG. 1A is a plan view of cooling pad 20, which is distinguished from cooling pad 20 of FIG. 1 principally by the inclusion of flow-directing welds. This primarily represents a second preferred embodiment of various aspects of the present invention. For reference, cooling pad 20 is also formed with a perimeter weld 38 surrounding the perimeter of the array 37, which seals the perimeter of sheets 30 and 31 together.

A further variation of the embodiment shown in FIG. 1 is illustrated in FIG 1A. This variation is the configuration of the liquid line quick disconnected fittings 28a, 28c, 29a and 29c. As can be seen in FIG. 1, the fittings 28a and 29a are both male in gender for convenient connection to conventional hyper-hypothermia units. However, FIG. 1A illustrates an alternative embodiment wherein one fitting, 28a is male in gender and the other fitting, 29a is female. With this embodiment, the heat exchanger pads can conveniently be connected together, without the use of gender

changing adapters. Those of skill in the art will readily recognize that the embodiment illustrated in FIG. 1 can also be connected to another like heat exchanger through the utilization of male-to-male gender adapters.

The tooling for RF-welding exchanger 23 is preferably of the conventional tear-and-seal type. As such, the tooling both forms the welds 33 and cuts the holes 35, 36 in a single operation, thereby minimizing the need for indexing and registry of the material between stamping and cutting operations. Because of the symmetrical nature of array 37, exchanger 23 can be formed using a two-stage process of stamping one lateral side of array 37, flipping the array 37 over, and then stamping the opposite lateral side of array 37. Such a two-stage forming process may help reduce tooling costs.

Full-length tabs 24 and 25 are also formed at each lateral edge of pad 20 and are equipped with hook-and-pile strips 41-46 to enable connection to adjacent pads, such as shown in FIG. 3. Hook and pile connectors strips are mounted on the opposing tabs 24 and 25, three on each side, the tabs are attached with pressure sensitive adhesive. Hence, three or four pads may be connected in series to provide a full-length patient cooling pad for providing a heat transfer thermal layer beneath the full-length of a patient laying a therapeutic support. Although separate hyper-hypothermia units could be provided for each pad in such a series, the same series may be served by a single unit by connection of the liquid lines in the manner shown in FIG. 3.

Liquid lines 28 and 29 are conventional liquid lines suitable for conveying cooling liquids pumped by a conventional hyper-hypothermia unit (not shown). Conventional ¼-inch I.D. by ⅜-inch O.D. clear 70F non-toxic PVC tubing is suitable for lines 28 and 29, such as is available under the "Kuri Tec K010" designation from Accuflex, Canada. The distal ends 28a and 29a of liquid lines 28 and 29 are adapted with quick-disconnect fittings 28a and 29a, respectively, for operative connection to the outlet and inlet of a hyper-hypothermia unit (not shown). Male CPC fittings are suitable for fittings 28a and 29a. Fittings 28a and 29a are preferably of the type that

have integral check valves that close when the fittings 28a, 29a are not operatively engaged within a corresponding female connector. This serves to minimize leaks of cooling liquid upon disconnect of lines 28 and 29 from the hyper-hypothermia unit. Line 28 is intended for connection to the outlet of the hyper-hypothermia unit, for receiving a flow of cooling liquid from the hyper-hypothermia unit. Line 29 is intended for connection to the return inlet of the hyper-hypothermia unit, for returning the flow of cooling liquid to the hyper-hypothermia unit. In the preferred embodiment, however, fittings 28a and 29a are identical and their connections to the hyper-hypothermia unit may therefore be reversed. In alternate embodiments, one of the two fittings 28a, 29a may be replaced or distinguished to ensure consistent connection of lines 28 and 29 to the respective outlet and inlet of the hyper-hypothermia unit. Appropriate adaptation of the lines from the hyper-hypothermia unit may be required to accommodate sealed connection with the particular fittings 28a and 29a.

The proximal ends 28b and 29b of liquid lines 28 and 29 are integrally bonded to the perimeter of heat exchanger 23, in a manner which communicates cooling liquid from lines 28 and 29 into an array of liquid passages therein. The integral connection is preferably achieved by inserting the proximal ends of lines 28 and 29 between the two opposing sheets of exchanger 23. Once so inserted, the proximal ends are welded in place by a separate R-F welding operation, welding the proximal ends between opposing sheets of exchanger 23. Such welding seals the lines into sealed communication with the enclosed array of exchanger 23.

In FIG. 1A, the lines 28 and 29 are, in turn, connected to the outlet and inlet of a hyper-hypothermia unit (not shown). Female CPC fittings are suitable for fittings 28a and 29a. Fittings 28a and 29a are preferably of the type that has integral check valves that close when the fittings 28a, 29a are not operatively engaged within a corresponding male connector, to minimize leaks of cooling liquid upon disconnect of lines 28 and 29 from the hyper-hypothermia unit. Line 28 is intended for connection to the outlet of the hyper-hypothermia unit, for receiving a flow of cooling liquid from

the hyper-hypothermia unit. Line 29 is intended for connection to the return inlet of the hyper-hypothermia unit, for returning the flow of cooling liquid to the hyper-hypothermia unit. In the preferred embodiment, however, fittings 40 and 41 are identical and their connections to the hyper-hypothermia unit may therefore be reversed. In alternate embodiments, one of the two fittings 40, 41 may be replaced or distinguished to ensure consistent connection of lines 28 and 29 to the respective outlet and inlet of the hyper-hypothermia unit. Appropriate adaptation of the lines from the hyper-hypothermia unit may be required to accommodate sealed connection with the particular fittings 28a and 29a.

A preferred embodiment of a complete patient cooling system includes at least one cooling pad 20, operatively connected to a conventional hyper-hypothermia unit. The "Blanketrol II," Model 222R unit (available from Cincinatti Sub-Zero Products, Inc., of Cinicinatti, Ohio) is an example of a conventional hyper-hypothermia unit with which pad 20 may be used in a preferred cooling system. Non-specific references in these describe a "standard" or "conventional" hyper-hypothermia unit or cooling unit should be understood to include units of that type. Liquid lines 128 and 130 are conventional liquid lines suitable for conveying cooling liquids pumped by a conventional hyper-hypothermia unit. (FIG. 13)

Referring to FIG. 3, as with other thermal layers, the primary function of cooling pad 20 is the enable circulation of thermal heat transfer liquids over an area in proximity to a patient to permit heat transfer between the patient and the liquid. Cooling pad 20 is considered to be "transmissive" in that air and water vapor are allowed to pass through one phase separate cooling pad 20 to the other phase thereof. The transmissive feature of cooling pad 20 enables use of pad 20 between the lower surface of a patient 15 and the upper surface of a therapeutic support 10, hence, can allow low air surface to pass into proximity with the patient and thereby allowing moist vapor to be evacuated from the patient's skin environment in order to enhance the micro-climate for optimal patient skin condition.

According, FIG. 3 is a plan view of cooling pad 20 as operatively implemented together with identical pads 21 & 22 for cooling patient 15 (shown in phantom line) supported on mattress 10 (shown in dashed line). As shown in FIG. 3, pads 20a, 20b and 20c are identical and are positioned adjacent each other utilizing the releasable hook and pile tabs to ensure their positioning.

As illustrated in FIG 2, other aspects of the present invention are appreciated by modifying or replacing the composition of sheets 30 and 31, or by otherwise combining different materials with pad 20. Particularly, in one alternative embodiment an absorptive pad (not shown) is secured to the outer surface 30a of the lower sheet 30 of heat exchanger 23. Vapor-permeable absorptive pads are preferred, such as are commercially available under the "DRIFLO" trademark from KCI Therapeutic Services, Inc. of San Antonio, Texas. Although adhesives or the like may be used for more secure mounting of such an absorptive pad on surface 30a, Applicant has found that the hook-matrix strips 44-46 of tab 25 tend to releasably engage the fabric of said preferred absorptive pads. Hence, to secure such a preferred absorptive pad to pad 20, the absorptive pad is laid flat in the center of mattress 10, and pad 20 is then positioned on top of the absorptive pad, in general region with the absorptive pad but in a position such that tab 25 overlaps an edge of the absorptive pad. When patient 15 is then positioned on pad 20 (or when strips 44-46 are otherwise pressed against the absorptive pad), the absorptive pad is releasably secured to the outer surface 30a of pad 20 by strips 44-46. Such releasable securement services to ensure optimal positioning directly beneath pad 20. Thence, the absorptive pad can not only be used to absorb incontinence and other body fluids, but it is also ideally positioned to absorb condensation that may collect on pad 20. Due to the releasable securement, the absorptive pad can then be removed, discarded and replaced as a disposable separate from pad 20, which is likely to be reusable.

Rather than (or in addition to) the above-described combination of a "DRIFLO" pad together with pad 20, similar purposes are addressed in another alternative embodiment by bonding an absorptive layer (not shown) on the outer

surface 30a of the lower sheet 30 of heat exchanger 23, FIG. 2. Using a thin sheet of PVC foam material as the absorptive layer, such a construction is perhaps best achieved by using an adhesive to bond the absorptive layer to surface 30a *before* the RF welding process (described elsewhere herein) such that the absorptive layer may be welded and cut in place at the same time as sheets 30 and 31. In use, pad 20 can then be positioned on mattress 10 with the absorptive layer facing away from the patient 15 with the hope of drawing moisture away from patient 15. With this configuration (as well as with the "DRIFLO" combination described previously), the absorptive layer is able to also serve the additional purpose of insulating pad 20 from heat that might be conducted or radiated from mattress 10. For that matter, such an absorptive layer would also help insulate pad 20 from heat that might be conducted or radiated from anywhere else outside surface 30a, such as from a lamp above the patient if pad 20 is placed on top of patient 15 or is wrapped around part of the patient 15.

Other aspects of the present invention are appreciated by bonding an insulative layer (not shown) on the outer surface 30a of the lower sheet 30 of heat exchanger 23. Using a thin sheet of PVC foam material as the insulative layer, such a construction is perhaps best achieved by using an adhesive to bond the insulative layer to surface 30a *before* the RF welding process (described further herein) such that the insulative layer may be welded and cut in place at the same time as sheets 30 and 31. In use, pad 20 can then be positioned on mattress 10. For that matter, such an insulative layer would also help insulate pad 20 from heat that might be conducted or radiated from anywhere else outside surface 30a, such as from a lamp above the patient if pad 20 is placed on top of patient 15 or is wrapped around part of the patient 15.

FIG. 4 is a partial, headward perspective view of an oscillatory patient support platform 10 having cooling pads 60, 70, 80 and 90 operatively positioned thereon, representing alternate embodiments of various aspects of the present invention. There is shown in FIG. 4 a therapeutic support platform apparatus 10 of the general type shown in U.S. Patent Nos. 3,343,165 issued to F.X. Keene on March 25, 1969,

4,175,550 issued to James R. Leininger et al. on November 27, 1979, and 4,730,606 issued to Peter A. Leininger on March 15, 1988 as depicted in FIG 11. Each of such U.S. patents are incorporated hereinto for any and all purposes by this specific reference. Preferably, support platform 10 is a device commercially available as a Roto Rest Delta unit from KCI Therapeutic Services, Inc. of San Antonio, Texas.

As illustrated in FIG. 12, the therapeutic support platform apparatus 10 includes a support surface 12 operably connected to a support frame 14 in a manner to permit oscillation of the support surface 12 relative to the support frame 14. The therapeutic support platform 10 has head retention members 16, side retention members 18a, 18b, 18c and 18d and feet retention members 17 all of which are positionably connected to the support surface 12.

Between side retention members 18a and 18b are pressure reduction inserts 13a, of a foam material, for example, to support arms of a patient when disposed in a supine position upon the therapeutic support platform apparatus 10. Likewise, between side retention members 18c and 18d are pressure reduction inserts 13b to support legs of a patient. Also, between side retention members 20 of the therapeutic support platform are a rectal pressure reduction insert 11 and a top pressure reduction insert 13b. There also is a head pressure reduction insert 01 disposed between head retention members 16. While a number of inserts are shown for use with the therapeutic support platform 10 in order to accommodate different applications, it is understood that the number of inserts and material therefor may vary according to the desired need. For example, the pressure reduction surface insert could be a single piece configured to fit between the retention members 16, 18a, 18b, 18c, 18d and 17. Also, it is contemplated that the contours of the pressure reduction surface inserts can be varied as desired.

As shown in FIGs. 5-6, there is a thermally controllable leg wrap 60 made of a generally flexible fluid impermeable material, such as in earlier embodiments. The wraps are configured for use with the leg pressure reduction insert 13b. The leg wrap 60 has a first side 03 having a portion 09 positionable adjacent the patient support

surface 12, a second side 05 having a first portion 04 thereof sealably connected to a first portion 06 of the first side 03 and a second portion 08 thereof spaced from a second portion 05 of the first side 03 such that there is formed a pocket 50 therebetween. Valves 67a and 68b with associated feed line 67 and return line 68 are operably connected through the proximal ends of 63 and 64 and connectable to a hyper-hypothermia fluid producing device as seen in FIG. 13 and described hereinafter to permit fluid flow therebetween.

The leg wrap 60 has pairs of oppositely disposed arms 60, 62, 64 and 66, wherein each arm has a hook and pile fastener, 68, to permit fastening to itself or other cloth material. Arms 60 are used to envelop the leg pressure reduction insert 30. Arms 62, 64 and 66 are used to wrap about the patient's leg when disposed thereon.

As shown in FIGs 7 and 8, there is a thermally controllable midsection wrap 70, made of a generally flexible fluid impermeable material suitable for containing and directing the flow of liquids such as may be used for cooling patients. This material has been described in earlier embodiments. FIGs 7 and 8 show a rectal wrap 70, having a retention sleeve 72 formed thereon to retain the rectal pressure reduction insert 11. Valves 76 with associated feed line 77 and return line 78 are also provided. As noted earlier, pad descriptions may be different and it should be understood that modifications do not depart from the scope of the invention.

FIG. 9 shows an upper body wrap 80 having retention sleeve 82 formed thereon to retain the top pressure reduction insert 84. Valves 86 with associated feed line 87 and return line 88 are also provided. The upper body wrap is made of a generally flexible material to permit fluid flow there between as described in earlier embodiments. Again it should be noted that pad descriptions may be different and modifications do not depart from the scope of the invention.

As with the other embodiments, FIG. 10 shows a head member 90 having retention sleeve 92 formed thereon to retain the head pressure reduction insert 95. Valves 96 with associated feed line 97 and return line 98 are also included in this pad design. Again, as with earlier embodiments, this pad is made with a generally flexible

material as describe earlier and modifications to pad design do not detract from the scope of the invention.

FIG. 11 is yet another alternate embodiment, a pad such as cooling pad 20 is comprised of multiple layers of liquid passages which may be utilized in an alternating fashion to circulate heat transferred liquid first in one pattern and then a second pattern. The member 100 similarly has a first side 102 positionable adjacent the patient support surface 12, a second side 104 having a first portion 106 thereof sealably connected to a first portion 108 of the first side 102 and second portion 110 thereof spaced from a second portion 112 of the first side 102 such that there is formed a pocket 114 therebetween. Also, within the meeting surfaces 106 and 108 are open surfaces 116. Valves 118 with associated lines 120 are operably connected to the pocket 114 and connectable to hyper-hypothermia fluid producing device FIG. 13 to permit fluid flow therebetween. In an alternative embodiment (not shown), openings 116 may be replaced with alternate means for enabling evacuation of vapor of adjacent the patient's skin or to provide limited airflow in the same proximity.

Many variations in the design and configuration of the wraps 60, 70 and 80 and members 90 and 100 may be employed. For example, the material thereof as well as the fluids and fluid flow patterns formed there within can be altered as desired. It may also be that separate fluid flow patterns may be formed in a single wrap or member wherein the flow patterns can be fed with different fluids or can be altered using a timed value mechanism which switches the fluid paths after a predetermined period or as desired to provide changes in surface temperature and pressure.

Moreover, one flow pattern may be air filled and the wrap or member may include restricted open surfaces along the flow pattern through which the air could continuously pass to further aid the patient. Optionally, multiple like wraps can be overlaid one on top of the other, if desired, such that the fluid flow patterns are slightly offset to create still another effect.

Referring to the schematic in FIG. 13, connected to the frame 14 are manifolds 122, 124 and 126 which are interconnected by feed lines 128 and return lines 130.

The feed lines 55 and 77 and return lines 56 and 78 are connected to a main manifold 122. Feed line 87 and return line 88 connect to top manifold 124 and feed line 97 and return line 98 connect to head manifolds 126.

Feed lines 132 and return lines 134 connect the hyper-hypothermia fluid producing device 58 to the main manifold 122. The number of lines and manifolds are set forth by way of example and it is understood that their number may increase or decrease as desired.

FIG. 4 shows the wraps operatively disposed within the therapeutic support platform apparatus 10. Once the patient is disposed on the wraps 60, 70, 80 and 90, the patient is covered, if so desired, and fluid flow is initiated through the wraps 60, 70, 80 and 90 via the hyper-hypothermia fluid producing device 58 as described above. Concurrently with the present invention or as desired, the therapeutic support platform apparatus 10 can be operated to provide treatment, such as oscillatory or traction therapy.

By so providing, the present invention has resulted in an improved thermally controllable apparatus for use with a predetermined therapeutic support platform apparatus and a thermal fluid producing device. The thermally controllable apparatus enables the patient to be cooled or heated and/or aired while receiving treatment on a therapeutic support platform apparatus.

The above described embodiments are set forth by way of example and are not for the purpose of limiting the present invention. It will be readily apparent to those skilled in the art that obvious modifications and variations can be made to the embodiments while still capturing novel aspects of the invention and without departing from the scope of the invention. Accordingly, the claims appended hereto should be read in their full scope including any such modifications and variations as well as equivalents to the elements claimed. When reading these claims, do not be constrained by any particular word or phrase, but consider them as far-reaching as the law will permit in light of any particular prior art reference that may be in the same particular field of art.

CLAIMS

What is claimed is:

1. A thermally controllable apparatus for use with a therapeutic support platform configured to support a patient thereon, which comprises:

a thermal fluid supply apparatus;

a first side and a second sheet, the first sheets being disposed adjacent the therapeutic support platform, and the second sheet being disposed adjacent the patient, the first sheet having a first portion thereof sealably connected to a first portion of said second sheet and a second portion thereof spaced from a second portion of said first sheet such that there is formed a pocket therebetween, wherein said first sheet and said second sheet form a thermally conductive member with vapor passages therethrough; and

a fluid port operably connected between said pocket and the thermal fluid producing device to permit fluid flow therebetween.

2. The apparatus of claim 1, wherein,

the vapor pasages defined by said sheets are adapted to allow passage of gas therethrough.

3. The apparatus of claim 1, wherein,

the openings defined by said sheets are adapted to allow passage of water vapor therethrough.

4. A cooling pad for use with a device that produes a flow of chilled heat transfer liquid for cooling a patient, comprising,

a cooling pad adapted for placement directly under a patient lying on a lower air loss mattresses, said cooling pad being adapted with a relatively flat construction to enable placement between the low air loss mattress and the patient such that a first face of the cooling pad faces the low air loss mattress and a second face of the cooling pad faces the patient, the second face being opposite the first face said cooling pad defining an array of enclosed liquid passages for directing a flow of

chilled heat transfer liquid through an area directly beneath the patient, to cool the patient;

said cooling pad further defining a plurality of openings through the array of enclosed fluid passages, for enabling the passage of air, water-vapor, condensation and other fluids between the first and second faces of said cooling pad.

FIG.1

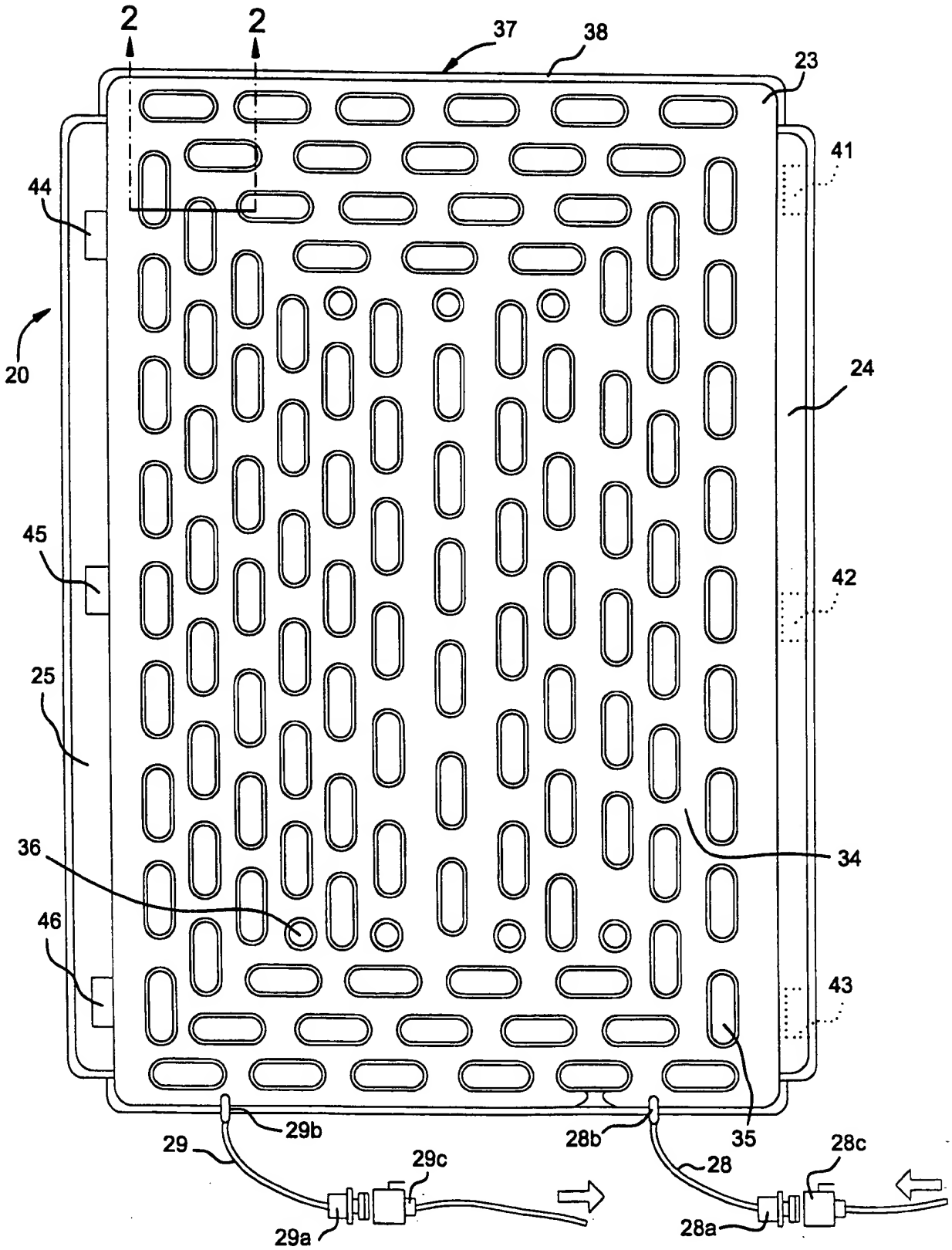

2
2
37
38
23
41
44
20
24
45
42
25
36
34
46
43
29b
29
28b
35
28c
29c
28
29a
28a

FIG.1A

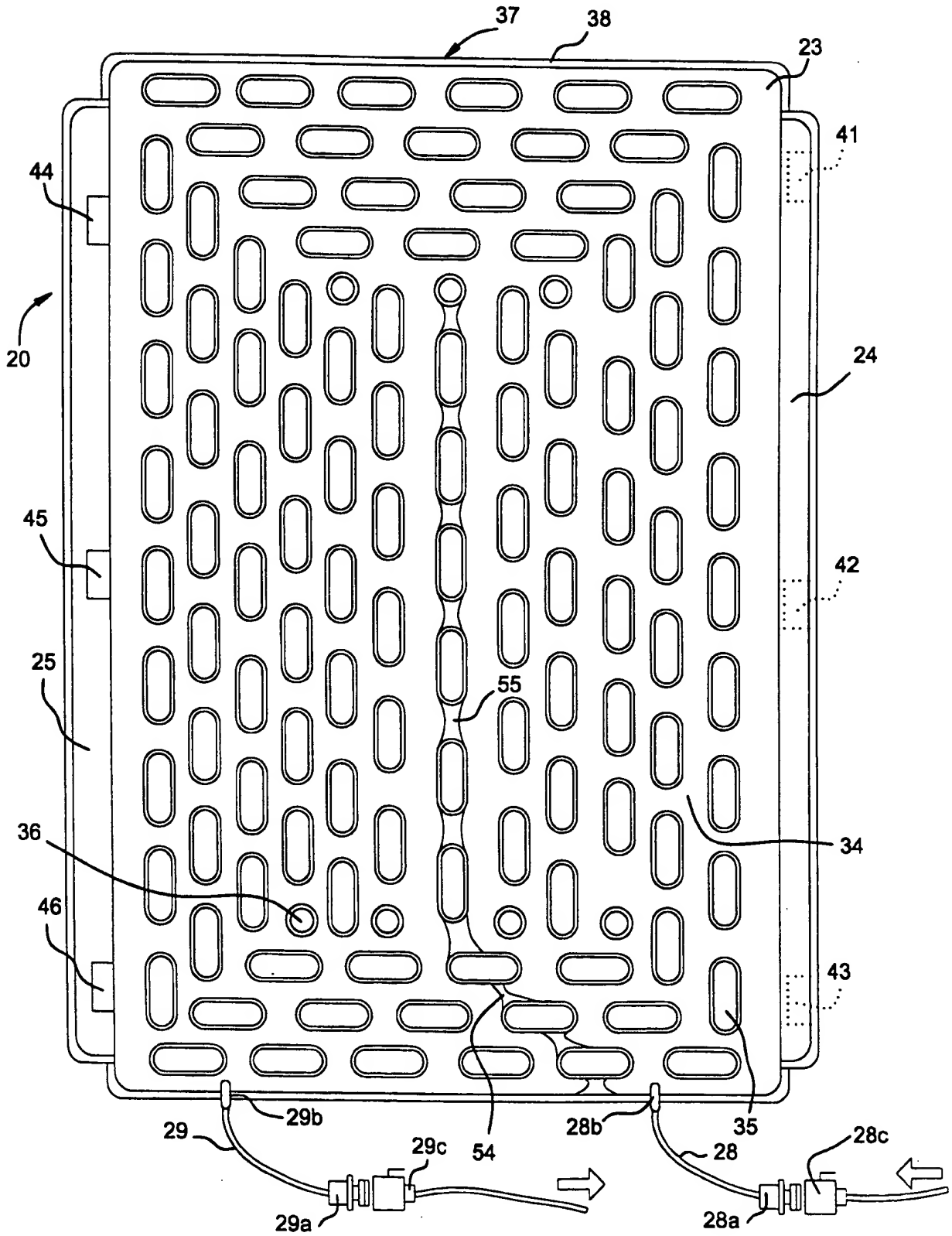

37
38
23
41
44
20
24
45
42
25
55
36
34
46
43
29b
29
28b
35
29c
54
28
28c
29a
28a

FIG.2

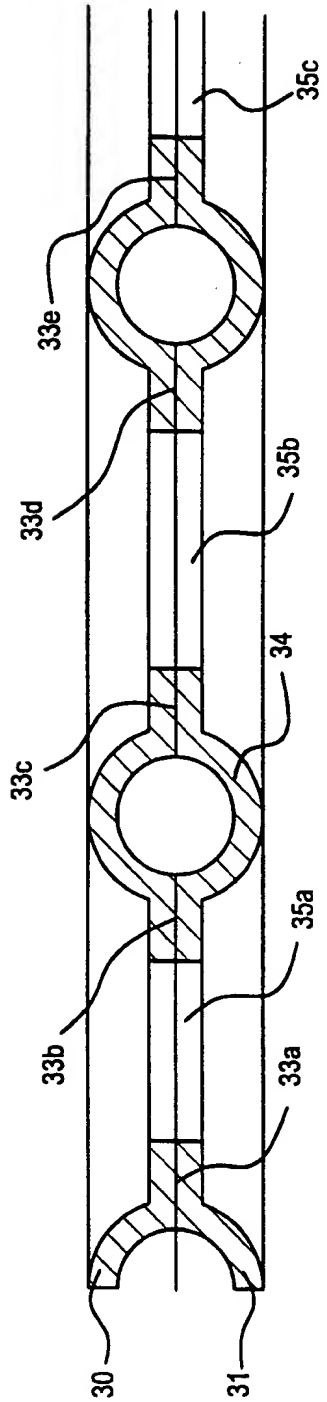


FIG.3

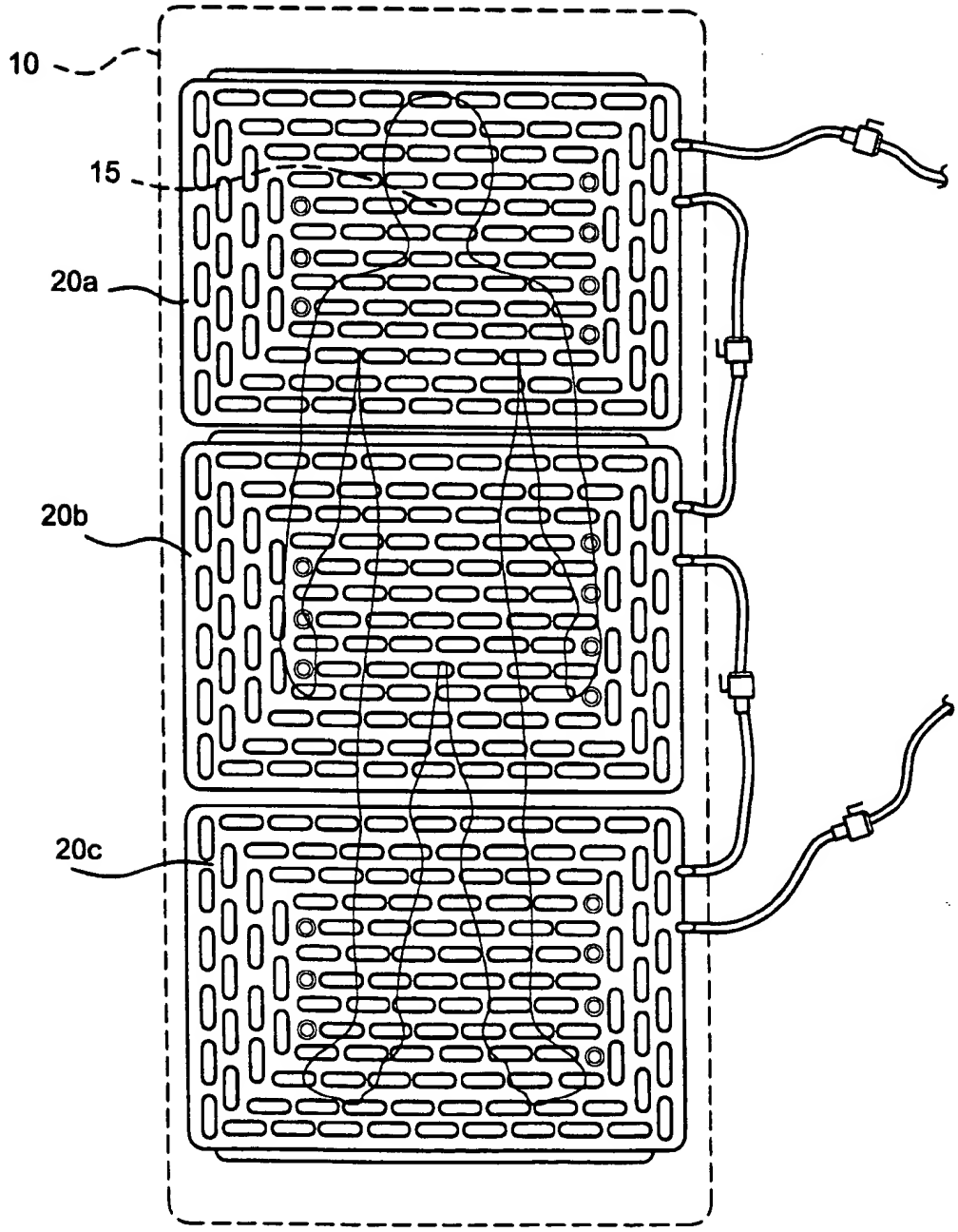


FIG.4

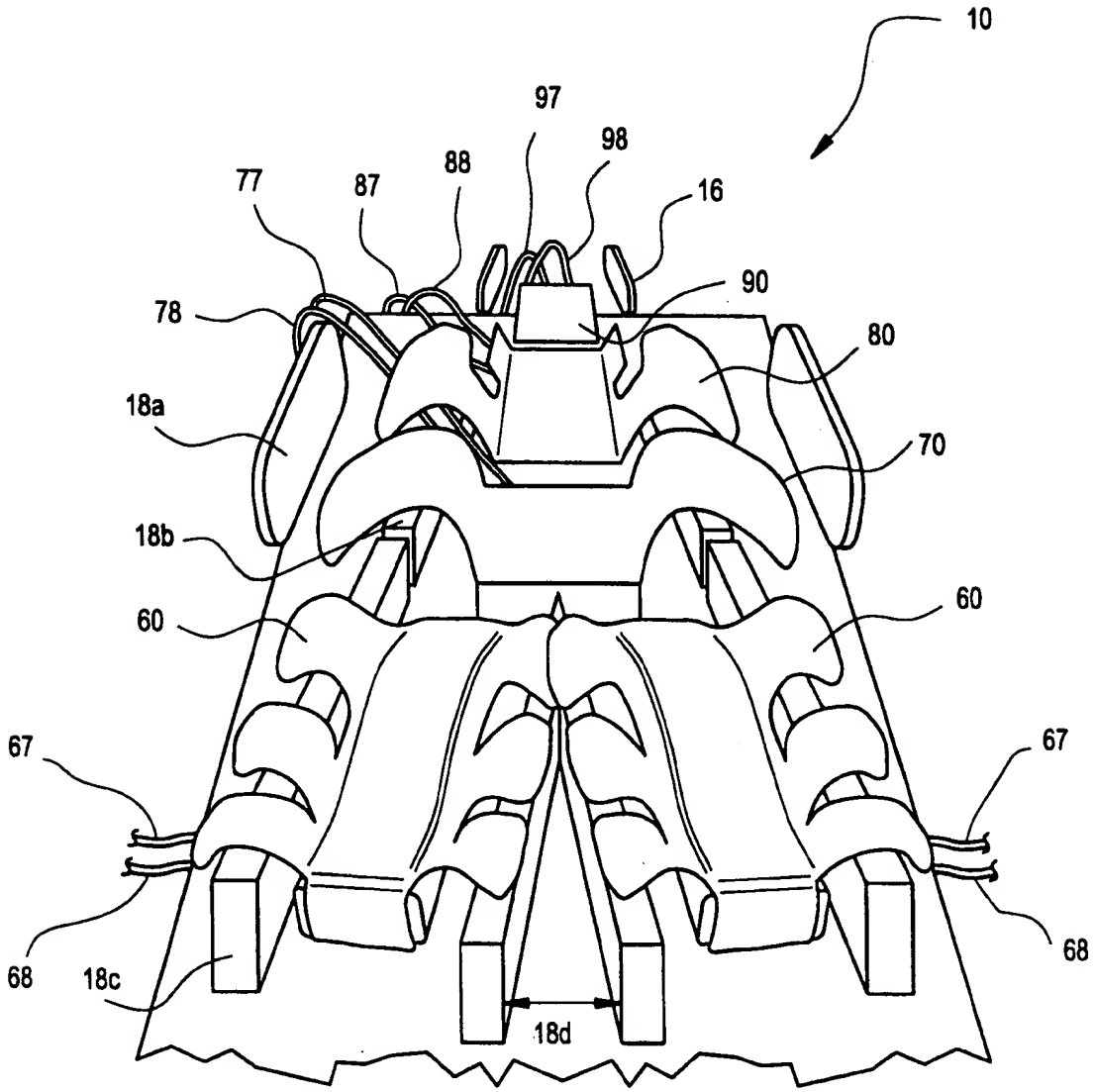


FIG.5

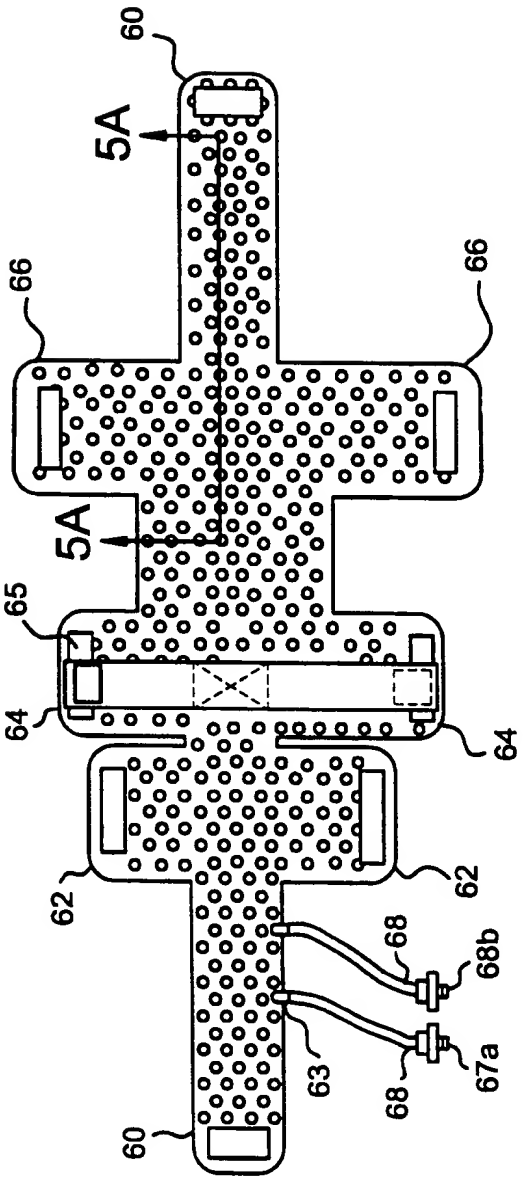

60
5A
66
66
5A
65
64
64
62
62
68
68b
63
68
67a
60

FIG.5A

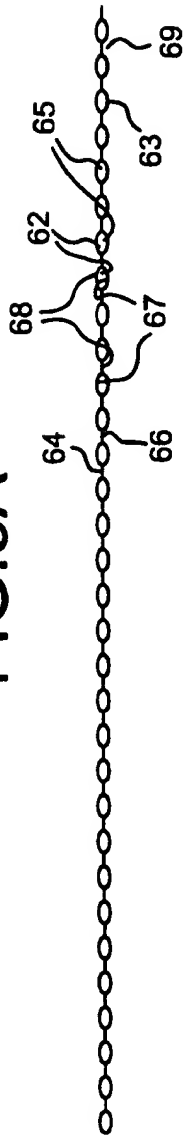

69
65
63
62
68
67
64
66

FIG.6

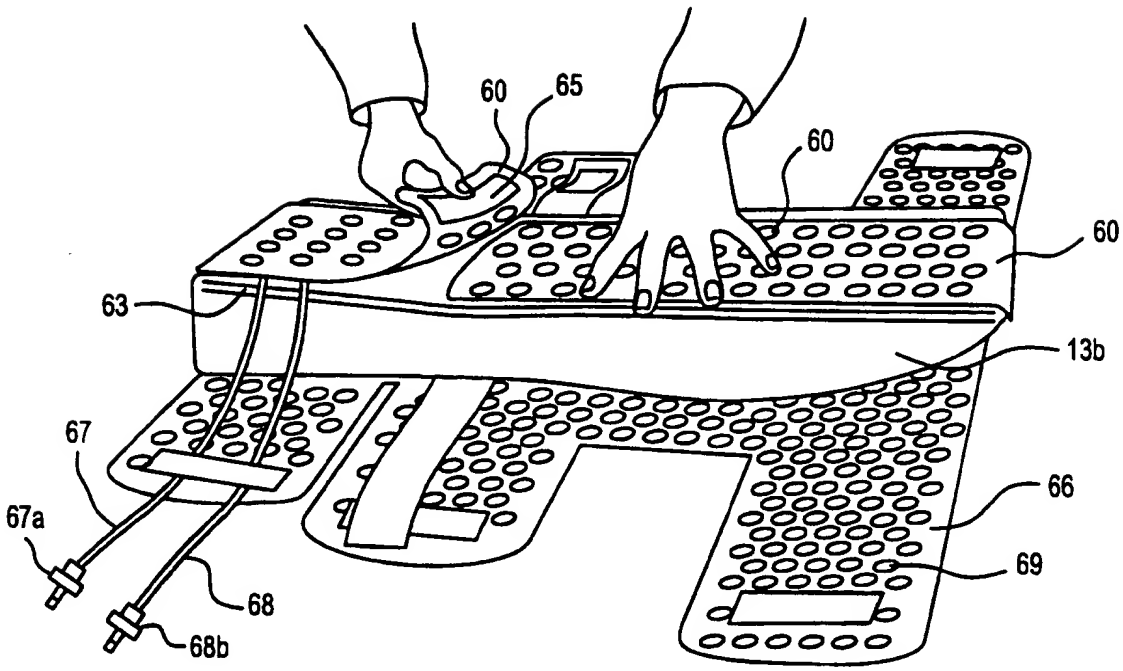


FIG.8

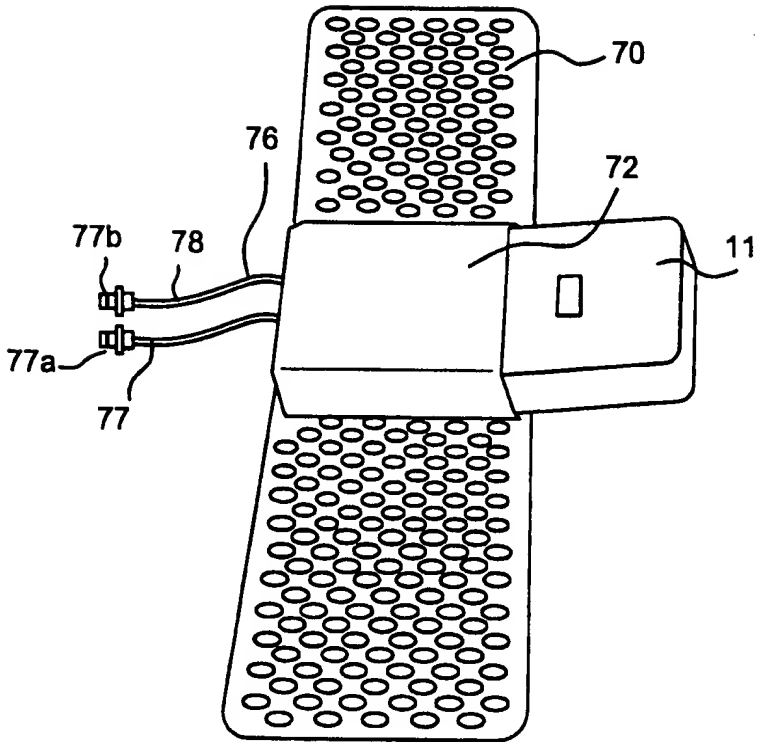


FIG.7

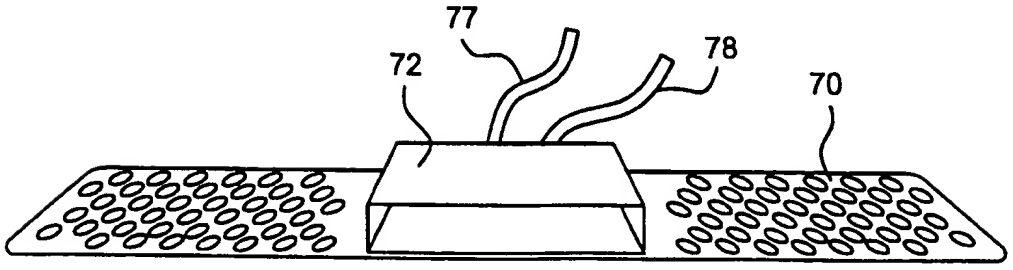


FIG.9

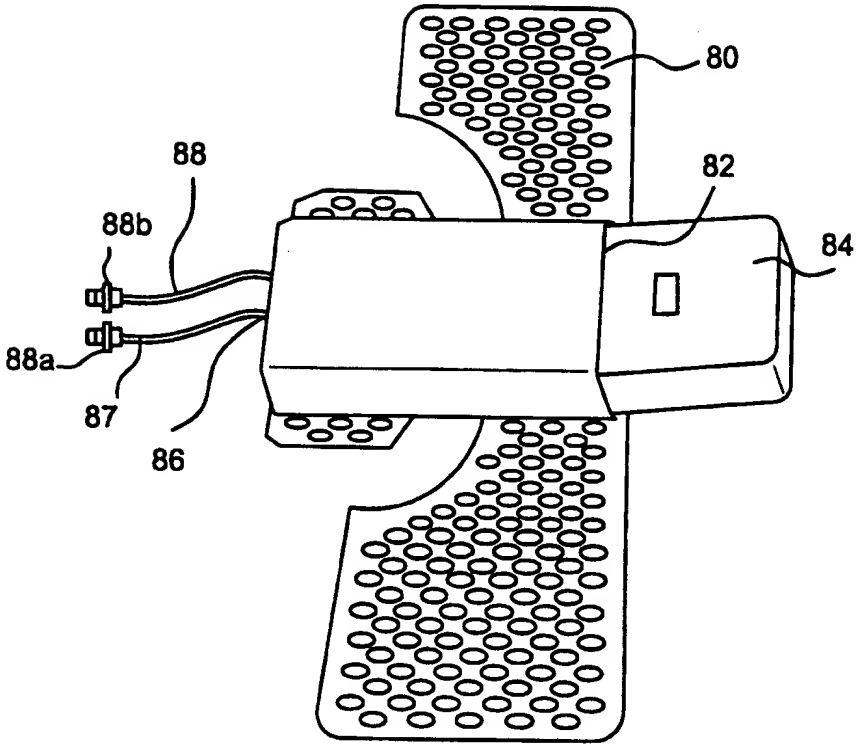


FIG.10

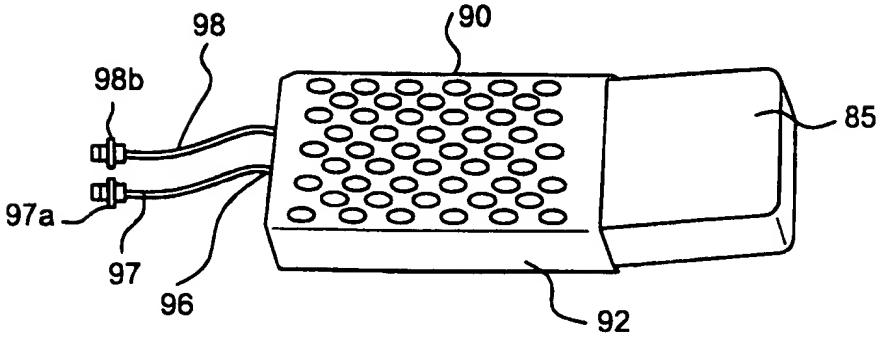


FIG.11

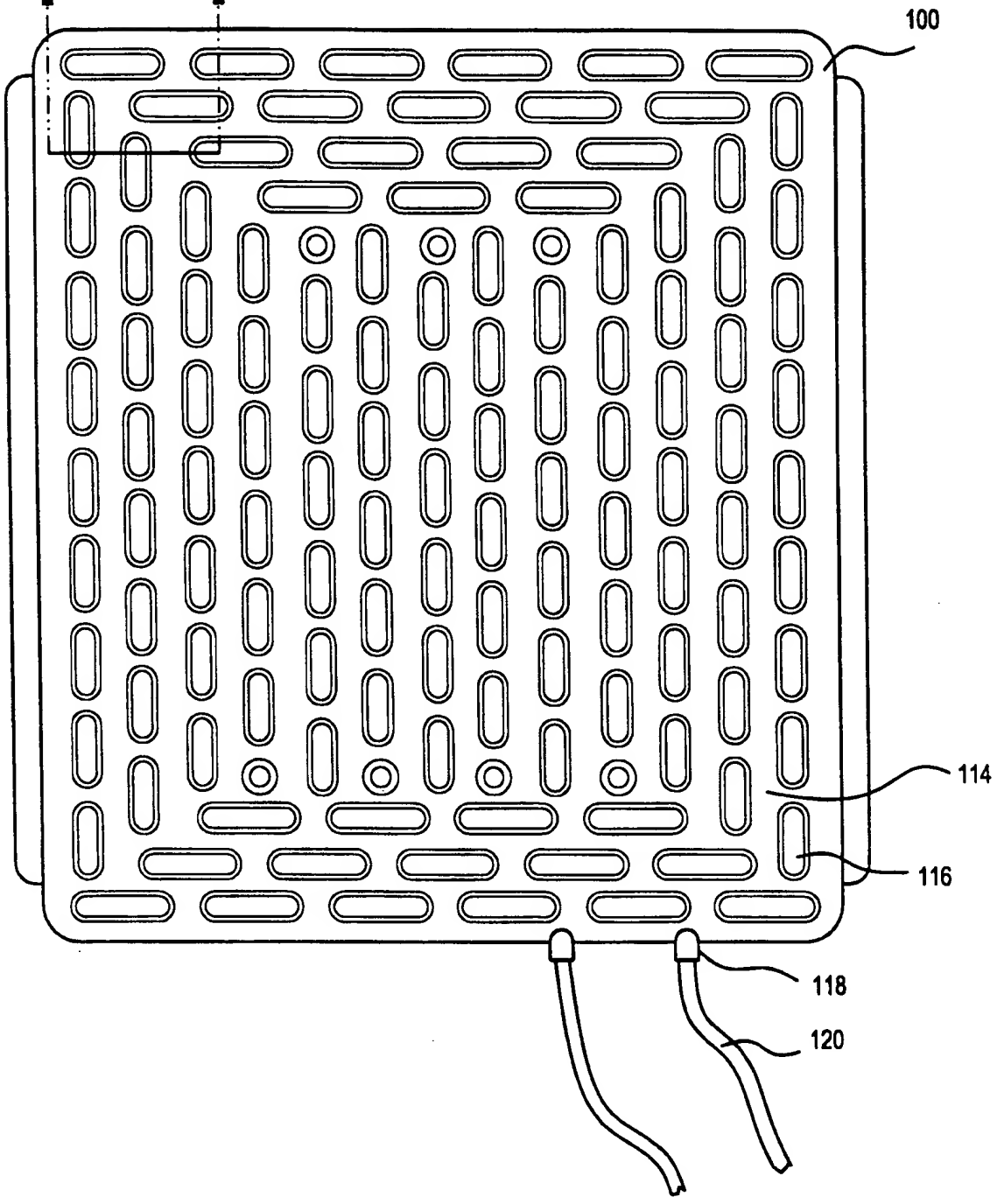


FIG.11A

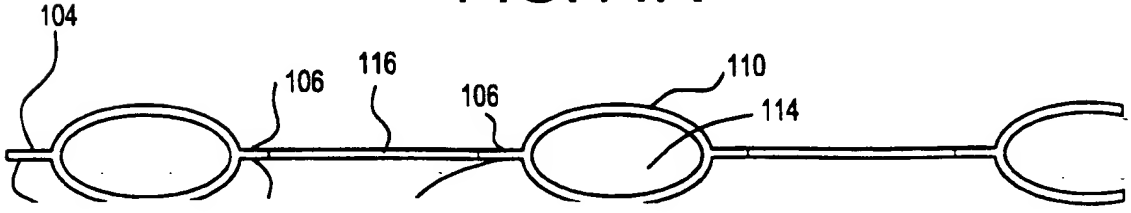


FIG.12

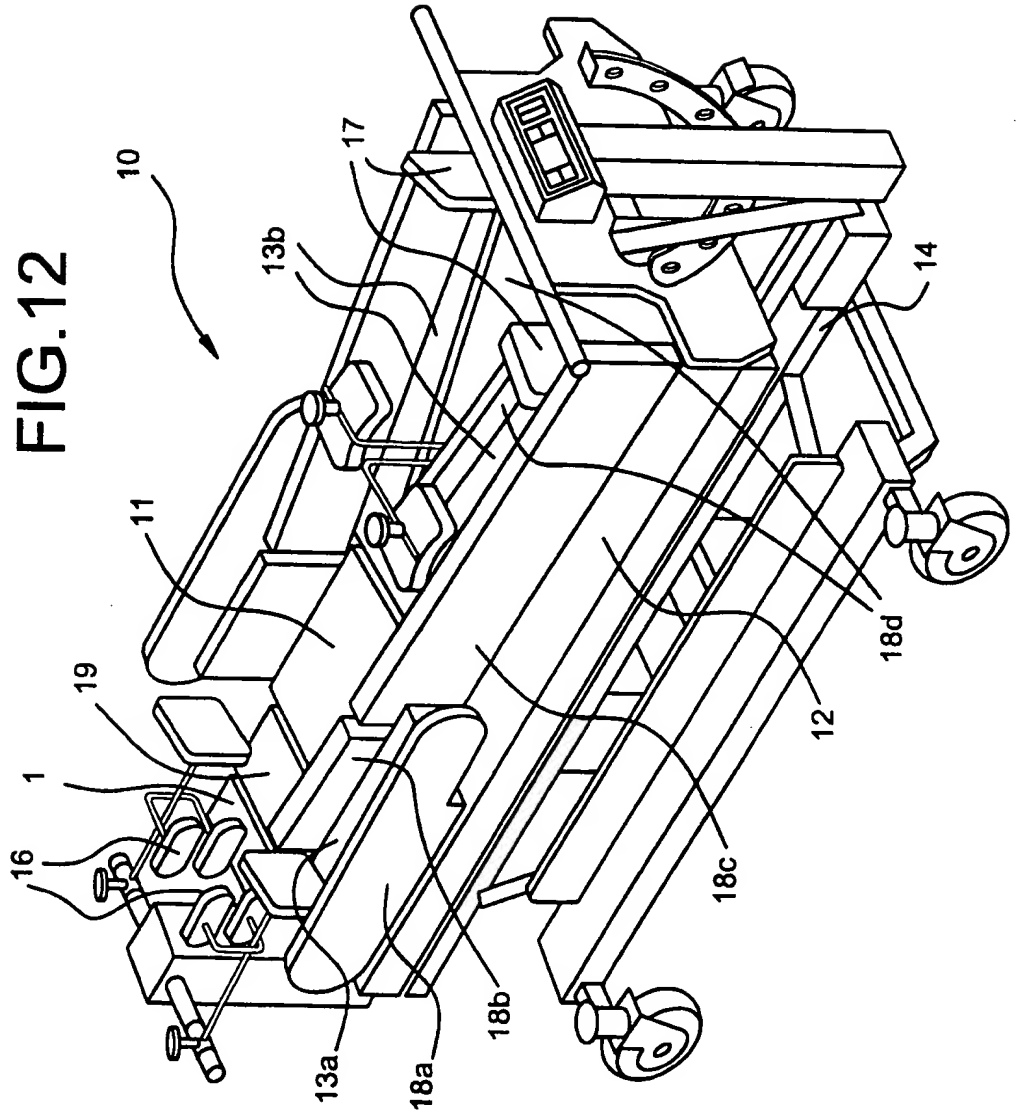
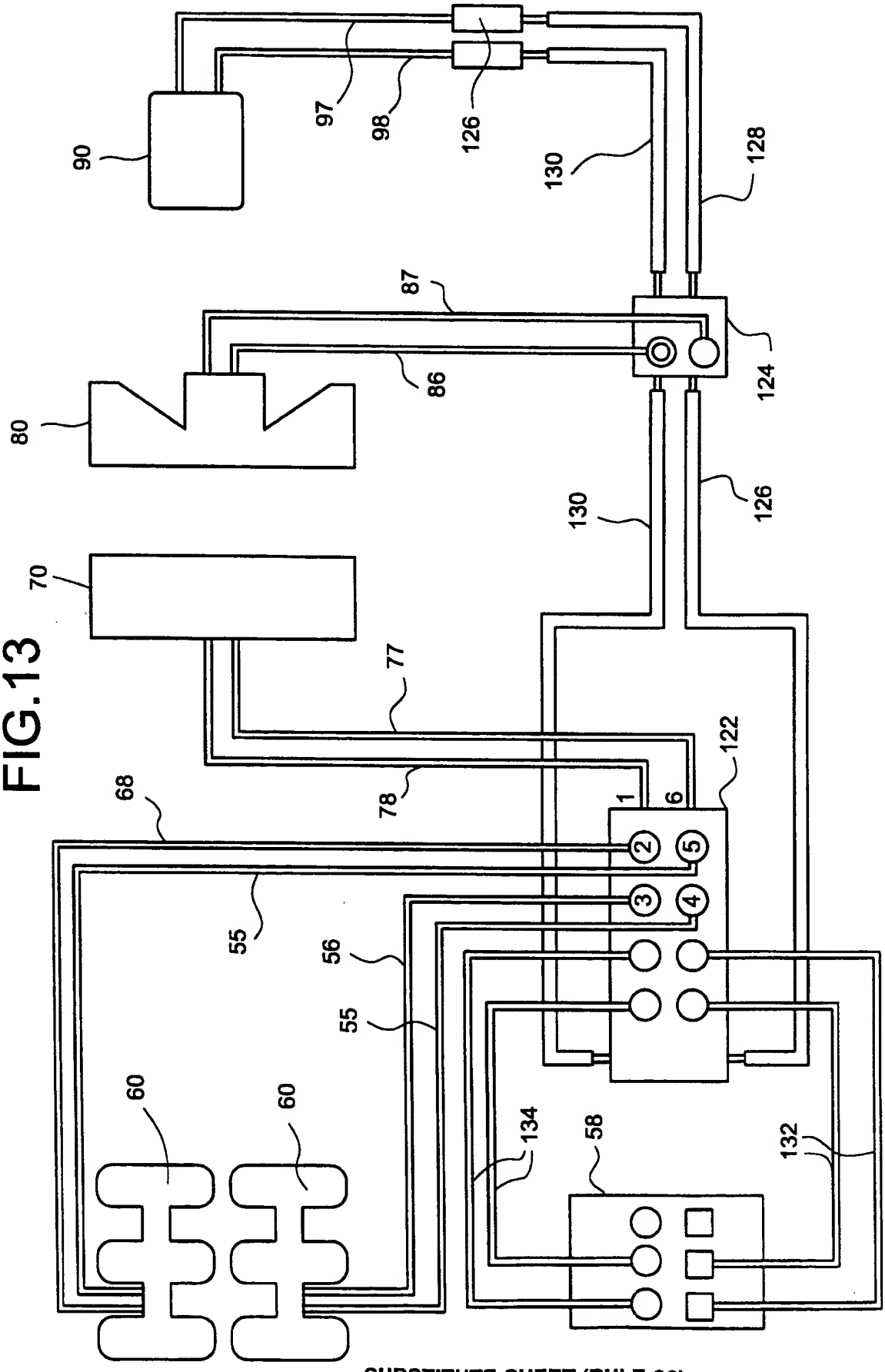


FIG.13


90
97
98
126
130
128
87
86
80
124
130
126
70
77
68
78
122
1
6
2
5
3
4
55
56
55
60
60
134
58
132

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/21760

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61F 7/00
US CL :126/204; 165/046; 607/104, 114

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 126/204; 165/046; 219/212; 607/104, 107-112, 114

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4,660,388 A (GREEN, JR.) 28 April 1987, entire document.	1-4
Y	US 4,459,468 A (BAILEY) 10 July 1984, entire document.	1-4

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 29 JANUARY 1998	Date of mailing of the international search report 23 FEB 1998
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer RYAN CARTER Telephone No. (703) 308-2990